

MAR 1 2006

SECTION 5 – 510(k) SUMMARY

K05.3640

[Submitted pursuant to 21 CFR 807.92(a). All data included in this document are accurate and complete to the best of DSC's knowledge.]

1. Submitter Information

Submitter: Direx Systems Corporation
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Canton, MA 02021

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Contact Person Larisa Gershtein
QA Manager

Contact Person e-mail address: lgershtein@direxusa.com

2. Device

Trade/Proprietary Name: Integra

Common/Usual Name: Extracorporeal Shock Wave Lithotripter (ESWL)

Regulation Number: 21 CFR 876.5990

Regulatory Class: Class II (special controls)

Product code: 78 LNS

Panel: Gastroenterology and Urology

3. Predicate Devices

Storz Modulith® SL-20/ (SLX) (P920051)

Storz Modulith® Lithotripter Model SLK (K010340)

Direx Tripter X – 1 Compact Duet (K041582)

Direx 3Dscope (K041213)

4. Intended Use:

The INTEGRA is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and upper ureter.

5. Description

INTEGRA is a transportable Electromagnetic (EM) Extracorporeal Shock Wave Lithotripter (ESWL) used for urinary stones treatment. The device is the result of integrating the cleared fluoroscopy imaging device - 3Dscope and lithotripter. INTEGRA also contains the necessary interfaces for ultrasonic imaging devices.

INTEGRA includes the following features:

- EM Shockwave generator with parabolic reflector for focusing mechanism
- High Level of integration: the shock wave generator is fully integrated with the fluoroscopic system and stationary patient table.
- In lieu of the patient table movement the reflector is moved in three directions
- In-line X-Ray localization system which is executed with lateral movement
- Off-line movable Ultrasound transducer

6. Performance Testing

The *Integra* Lithotripter was tested according to the following standards:

- IEC 60601-1 (1988) +A1 (1991) +A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2001)
- IEC 60601-1-3 (1994)
- IEC 60601-2-7 (1998)
- FDA CDRH 21CFR 1020.30
- FDA CDRH 21CFR 1020.32
- IEC 606001-2-36 (1997)
- IEC 61846 (1998)
- IEC 60601-2-38 (1996)

- ANSI/ AAMI/ ISO 10993– 1 (1998)
- CISPR 11 (1997) + A1 (1999) class B
- IEC 60601-1-4 (2000)
- Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; August 9, 2000

7. Clinical Tests

The Confirmatory study was conducted according to “Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; August 9, 2000, Chapter 8 subchapter D: (Clinical Performance Testing, confirmatory clinical study).

8. Substantial Equivalence

INTEGRA is substantially equivalent to the predicate devices, since the basic features, design and intended uses are the same or similar.

Specifically, The devices have the same intended uses (the Storz devices and Compact Duet).

In terms of generation and focusing of pressure waves Integra is similar to the Storz predicates. (both use parabolic reflectors that converge pressure waves to a focal point). Both Integra and Storz SL-20/ (SLX) have also the same shockwave orientation (the angle of reflector is 90°).

Similarly to the Storz devices, Integra contains an in-line X-ray localization system.

The Ultrasound localization is similar to that of Compact Duet in the sense that the ultrasound probe of both devices is located outside the reflector.

Most of the X-ray parameters are the same as the ones of 3Dscope.

The minor differences in design, dimensions and features between Integra and its predicates raise no new issues of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2006

Ms. Larisa Gershtein
QA Manager
DiREX Systems Corporation
437 Turnpike Street
CANTON MA 02021

Re: K053640
Trade/Device Name: *Integra*
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: December 27, 2005
Received: December 30, 2005

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Section 4: Indications for Use Statement

Indications for Use STATEMENT

510(k) Number (if known): K053640

Device Name:

Integra

Indications for Use:

The INTEGRA is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and upper ureter

Prescription Use X
(Per 21 CFR § 801.109)

OR

Over the Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

David A. Segrom
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053640